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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,851	05/28/2002	Horst Rapp	HMN 2 0021	8437

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,851	RAPP ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment and response filed on May 19, 2005 wherein claims 1-20 have been amended.

Currently, claims 1-20 are pending in this application.

Claims 1-20 as amended now are examined on the merits herein.

Applicant's amendment filed May 19, 2005 with respect to the rejection of claims 1-20 made under 35 U.S.C. 112 first paragraph for containing new subject matter which was not described in the original specification and claims, i.e., the particular disease "tinea pedis" of record stated in the Office Action dated November 17, 2004 have been fully considered and found persuasive to remove the rejection since the new matter, "tinea pedis", has been removed from the claims. Therefore, the said rejection is withdrawn.

Applicant's amendment filed May 19, 2005 with respect to the rejection of claims 1-20 made under 35 U.S.C. 112 second paragraph for the use of the indefinite recitation, i.e., a broad range or limitation together with a narrow range or limitation of record stated in the Office Action dated November 17, 2004 have been fully considered and found persuasive to remove the rejection since the indefinite recitation has been deleted from the claims. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Wakeman (3,317,540) for same reasons of record stated in the Office Action dated November 17, 2004.

Wakeman discloses that tosylchloriaamide(s) and its known derivatives are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection (see col.1 and col.3 lines 53-56). Wakeman discloses the pharmaceutical compositions of tosylchloriaamide(s) in a form, a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O?W or W/O-emulsion (see col. 2 line 32 to col.3 38).

Thus, Wakeman anticipates claim 20.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by DE 197 12 565 for same reasons of record stated in the Office Action dated November 17, 2004.

DE 197 12 565 discloses that tosylchloriaamide(s) and its known derivatives such as Chloramin T are useful in a pharmaceutical composition by topical administration to skin broadly and hair and thus useful in treating skin diseases herein (see Table at page 5 and claims 1-16). DE 197 12 565 also discloses the effective

amounts of the pharmaceutical compositions of tosylchloriaamide(s) (see Table at page 5 and claims therein).

Thus, DE 197 12 565 anticipates claim 20.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Vandevelde et al (WO 91/07876) for same reasons of record stated in the Office Action dated November 17, 2004.

Vandevelde et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-8 and claims 1-28). Vandevelde et al. discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-13 at page 9-20).

Thus, Vandevelde anticipates claim 20.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Harwardt et al (DE 41 37 544) for same reasons of record stated in the Office Action dated November 17, 2004.

Harwardt et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical

administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-4 and claims 1-7). Harwardt et al. discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-5 at page 3-4). Thus, Harwardt anticipates claim 20.

As indicated above, the recitation, "A medicament" in claim 20 will be examined as a pharmaceutical composition. Note that it is well settled that "intended use" of a composition or product, e.g., treating disease of the skin, will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Note that Applicant also admits that the rejections under 35 U.S.C. 102(b) of record in the previous Office Action are applicable to composition claims (see Applicant's arguments filed July 9, 2004).

Response to Argument

Applicant's arguments filed May 19, 2005 with respect to the rejections of claim 20 made under 35 U.S.C. 102(b) in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicant asserts that "[n]one of these references, however, disclose compositions containing tosylchloramide or salts thereof effective in treating the recited diseases of the skin". Note that Applicant also admits that "[i]t is true that the discovery of a new use or property of an old product does not render a composition claim patentable, but only if the old product inherently possesses the claimed property or is capable of performing the intended use". See Applicant's response at page 6.

Nonetheless, again, it is well settled that "intended use" of a composition or product, e.g., treating disease of the skin, will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

In this case, each cited reference discloses that the same tosylchloriaamide(s) and its known derivatives such as Chloramin T are useful in a pharmaceutical composition by topical administration to skin broadly and hair and thus useful in treating skin diseases herein.

A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The prior art teaches application to the skin of compositions containing the same components as instantly claimed, which would inherently treat skin diseases as instantly claimed. Applicant has not provided any evidence of record to

show that the prior art compositions do not exhibit the same properties as instantly claimed.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 102(b). Therefore, said rejections are adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9-13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakeman (3,317,540) for same reasons of record stated in the Office Action dated November 17, 2004.

Wakeman discloses that tosylchloriaamide(s) and its known derivatives are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection (see col.1 and col.3 lines 53-56). Wakeman discloses the pharmaceutical compositions of tosylchloriaamide(s) and their salts in a form, a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O?W or W/O-emulsion (see col. 2 line 32 to col.3 38). Saito et al. discloses that the particular adrenal enzyme inhibitor, trilostane, is useful in the pharmacological treatment of Cushing's syndrome by

reducing the steroid production in the patients showing severe hypertension and diabetes mellitus. See title and the English abstract of the Japanese journal article.

Wakeman does not expressly disclose the employment of tosylchloriaamide(s), in methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein, because tosylchloriaamide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection according to Wakeman. It is also well-known that the many instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus are caused by microorganisms and/or accompanied by microorganisms.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloriaamide(s) and their salts, the known antiseptics and disinfecting agents would have beneficial therapeutic effects and usefulness in methods of treating instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus, by antiseptic action and disinfecting the affected skin area through killing and destroying microorganisms.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandevelde et al (WO 91/07876) for same reasons of record stated in the Office Action dated November 17, 2004.

Vandevelde et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-8 and claims 1-28). Vandevelde et al. discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-13 at page 9-20).

Vandevelde et al. does not expressly disclose the employment of tosylchloriaamide(s), in methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein, because tosylchloriaamide(s) and their salts are known

to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus according to Vandevelde et al.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloriaamide(s) and their salts, being known in treating skin retrovirus, would have beneficial therapeutic effects and usefulness in methods of treating herpes simplex virus.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harwardt et al (DE 41 37 544) for same reasons of record stated in the Office Action dated November 17, 2004.

Harwardt et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-4 and claims 1-7). Harwardt et al. discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-5 at page 3-4).

Harwardt et al. does not expressly disclose the employment of tosylchloriaamide(s), in methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloriaamide(s) and their salts in methods of the particular skin diseases herein, because tosylchloriaamide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus according to Harwardt et al.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloriaamide(s) and their salts, being known in treating skin retrovirus, would have beneficial therapeutic effects and usefulness in methods of treating herpes simplex virus.

Response to Argument

Applicant's arguments filed May 19, 2005 with respect to the rejections made under 35 U.S.C. 103(a) of record in the previous Office Action November 17, 2004 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant argues that the cited references neither disclose nor suggest the use of tosylchloramide compounds in the treatment of the particular skin diseases or even diseases that are remotely similar.

Nevertheless, it must be recognized that any judgment on obviousness takes into account knowledge which was generally available and within the level of ordinary skill at the time the claimed invention was made. In this case, as pointed out in the previous Office Action, because tosylchloriaamide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection according to the cited prior. It is also well-known that the many instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus are caused by microorganisms and/or accompanied by microorganisms.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloriaamide(s) and their salts, the known antiseptics and disinfecting agents would have beneficial therapeutic effects and usefulness in methods of treating instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus, by antiseptic action and disinfecting the affected skin area through killing and destroying microorganisms.

Moreover, a chemical composition and its properties are inseparable. The burden is shifted to Applicant to show clear and convincing factual evidence of nonobviousness or unexpected results, i.e., side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejections are adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
July 28, 2005